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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/821,778	04/09/2004	Tomas Kara	630666.91161	1444

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QUARLES & BRADY LLP
411 E. WISCONSIN AVENUE
SUITE 2040
MILWAUKEE, WI 53202-4497

EXAMINER

KAHELIN, MICHAEL WILLIAM

ART UNIT	PAPER NUMBER
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3762

DATE MAILED: 05/10/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/821,778

Applicant(s)

KARA ET AL.

Examiner

Michael Kahelin

Art Unit

3762

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 March 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-29 is/are pending in the application.
- 4a) Of the above claim(s) 6-20 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-5 and 21-29 is/are rejected.
- 7) ☒ Claim(s) 1-5 and 21-29 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: _____

DETAILED ACTION

Claim Objections

1. Claims 1-5 and 21-29 are objected to because of the following informalities: consistent terminology should be used throughout the claims for the "vagus nerve stimulation signal". For instance, in claim 1, "vagus nerve stimulation pulse" should read "vagus nerve stimulation signal"; in claims 2, 24, 25, 26, 27, 28 and 29, "vagus nerve signal" should read "vagus nerve stimulation signal"; in claim 3, "the amplified input signal" should read "the amplified vagus nerve stimulation signal" or just "the amplified signal". Appropriate correction is required.

Claim Rejections - 35 USC § 112

2. The amendments to claims 2, 5, and 28 in response to the rejections under 35 USC 112(2) in the last Office Action are acknowledged and accepted. The rejections of claims 2, 5, and 28 under 35 USC 112(2) are withdrawn.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the

various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (9 or (g) prior art under 35 U.S.C. 103(a).

5. Claims 1-4, 21-24, 28, 29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Osorio et al. (US 6,341,236, hereinafter "Osorio") in view of Adkins et al. (US 5,928,272, hereinafter "Adkins"). Osorio discloses detecting vagus nerve stimulation, digitizing the signal, filtering the signal, and rectifying the signal (fig 10, col. 11, lines 18-39) but does not disclose amplifying the signal, prolonging the signal, electrically isolating the signal, comparing the filtered and rectified signal to a threshold value, detecting an analog signal such as ECG, or triggering the sampling of a physiologic signal such as ECG. Adkins teaches of amplifying a sensed signal from vagus nerve stimulation, and comparing the value to a threshold value (col. 8, line 52-col. 9, line 6). Adkins also teaches of triggering the sampling of a physiologic signal including ECG (col. 6, lines 54-67). It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the invention of Osorio by amplifying the VNS signal in order to achieve higher resolution when converting to digital form, to compare the signal to a threshold value in order to objectively determine whether VNS was taking place, and to trigger the sampling of ECG after the detection of

VNS in order to assure that physiologic function of the heart is unaltered, in which case the ECG would be a function of the VNS since the vagus nerve innervates the heart.

6. It is well known in the art to prolong the signal when converting a signal to digital form for later sampling and would have been obvious to one of ordinary skill in the art to prolong the signal in order to choose different sampling rates that exactly match those used by the A/D converter since sometimes A/D converters use variable sampling rates.

7. It is well known in the art to isolate sensed signals in order to prevent inadvertent shocking of the patient through the sensing circuit. Therefore, it would have been obvious to one of ordinary skill in the art to isolate the sensed signal in order to prevent inadvertent shocking of the patient.

8. Claims 5, 25-27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Osorio in view of Adkins as applied to claim 1 above, and further in view of Lo et al. (US 5,738,104, hereinafter "Lo"). Osorio and Adkins disclose the invention substantially as claimed but do not disclose an alarm signal indicating that the VNS has been detected, storing the physiological signal as a function of time, or displaying the physiologic signal and the filtered signal. Lo et al. teach an ECG machine with a display (fig 1, element 12) to notify the user of physiological electrical conditions (such as Fig. 11A, 11B and 11C from Osorio), which is interpreted to be a visual alarm signal as well as the displaying of the filtered and physiologic signals and Lo's invention is configured to store what was displayed in memory (col. 15, lines 7-27). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to further modify the invention of Osorio by including the display for displaying the physiological signal as

well as the filtered signal and storing these signals in order to visibly inspect the signal measured as well as review the signals measured at a future point in time by a physician.

Response to Arguments

9. Applicant's arguments filed 3/14/2006 have been fully considered but they are not persuasive. In regards to independent claim 1, Applicant argued that neither Osorio nor Adkins disclose monitoring a vagus nerve signal, but rather monitor an ECG signal. Therefore, the references in combination fail to disclose or teach each and every element of the claimed invention. However, referring specifically to column 11, line 26 of Osorio, it is very clearly indicated that the algorithm is for "detecting VNS-induced artifact in the EKG signal". Further, Osorio discloses at column 11, line 54 that "the system determines that the stimulation is "on" when $R(k) \geq 5$ and "off" when $R(k) < 5$ ". So, irrespective of whether the measured signal contains ECG data or not (which in this case is merely extraneous noise filtered out to acquire the VNS signal), Osorio meets the claim language.

Conclusion

10. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the

Art Unit: 3762

shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Kahelin whose telephone number is (571) 272-8688. The examiner can normally be reached on M-F, 9-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on (571) 272-4955. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

MWK



5/8/06


GEORGE R. EVANISKO
PRIMARY EXAMINER

5/8/06